REMARKS

In the amendments above, claim 1 has been amended to more clearly recite applicant's invention. No issue of new matter is raised by this amendments. Applicants respectfully request that the Examiner enter and consider this amendment. Upon entry of this amendment, claims 1-4 and 9, as amended, will be pending and under examination.

Rejection Under 35 U.S.C. 103

The Examiner rejected claims 1-4 and 9 under 35 U.S.C. 103(a) as obvious over WO 01/12161 ("Martani"). Specifically, the Examiner indicated that even though Martani does not explicitly disclose the claimed particle sizes, friability values, and proportion of insoluble elements, these would have been obvious to one of ordinary skill in the art.

In response, applicant respectfully traverses the Examiner's ground of rejection.

Applicant's invention as now claimed provides a tablet for oral administration that disintegrates quickly in the oral cavity in less than 30 seconds, comprising: i) spray-dried mannitol in a proportion of at least 59.5%; ii)active ingredient in a proportion below or equal to 10%, as a fine powder in which at least 90% in weight of the active ingredient has a particle size less than 100 μm; iii) microcrystalline cellulose in a proportion from 10 to 18%, with an average particle size of approximately 50 μm where at least 99% in weight of microcrystalline cellulose has a particle size below 250 μm; iv) sodium croscarmellose in a proportion from 1 to 4%; and v) a lubricant agent in a proportion from 0.5 to 2% in weight, where, unless specified otherwise, the percentages are expressed in weight of the total weight of the tablet, wherein said tablet has a friability below 0.5%.

Martani discloses a solid dosage form which rapidly dissolves in an aqueous medium, which dosage form comprises an active substance, mannitol, microcrystalline cellulose, croscarmellose Na and a lubricant, wherein such dosage form disintegrates within 30 seconds when taken into the mouth . As the Examiner acknowledges, Martani does not disclose the claimed particle sizes, friability values, or proportion of insoluble elements. Applicant maintains that in addition,

Martani also fails to disclose the claimed ratios or spray-dried mannitol.

Specifically, the application discloses that the "spray-dried" mannitol is a critical component of the claimed composition. The spray-dried mannitol is disclosed in the application by its physical properties, namely as being made up fundamentally of the crystalline form α. In addition, the application clearly indicates that for the present invention must contain at least 59.5% spray-dried mannitol. See page 7, line 19 to page 8, line 26 of the specification. In contrast, Martani does not disclose nor suggest a mannitol having fundamentally a crystalline form α, i.e. the spray-dried mannitol of the invention, in a tablet composition, or that it must be present at least at 59.5% of the tablet composition.

In addition to the above, page 7, line 34 to page 8, line 8 of the present application discloses "[t]he proportion of microcrystalline cellulose is from 10 to 18% in weight of the total weight of the tablet (...) and that higher quantities have a negative impact on the palatability of the formula and lower quantities worsen the capacity of the disintegration promoter". In contrast, Martani discloses the quantity of this filler (microcrystalline cellulose) as being at least 30% in weight of the total dosage form (page 11, line 24). Applicant maintains that such a ratio would have a negative impact on its palatability. The same also applies to the ratio of Na croscarmellose.

Accordingly, applicant maintains that the Examiner has not established a prima facie case of obviousness.

Nevertheless, applicant maintains that one skilled in the art would not have expected that a tablet comprising spray-dried mannitol present in a quantity of at least 59.5% to result in a tablet that is both quick-dissolving and has a friability below 0.5%. Accordingly, applicant maintains that the claimed tablet is an unexpected result based on what was known and expected in the art at the time this application was filed.

Because Martani is concerned with the difficulty of swallowing tablets, Martani discloses mannitol as an ingredient particularly useful in oral dosages at coadjuvating rapid disintegration

on contact in the mouth. However, Martani does not disclose that such a tablet is possible having a friability below 0.5%. In addition, the specification of the present application indicates at page 4, lines 7-13, that: "[s]urprisingly, the present invention has revealed that by using diluent of high dissolution rate and high compressibility, and limiting the proportion and size of the particle of the insoluble ingredients, mixtures with optimum compressibility can be obtained. These mixtures enable the obtaining of orally disintegrating tablets which disintegrate in the mouth in less than 30 seconds (...)". Moreover, analyzing the parameter of friability, as shown from the Tables of the present invention, when using "spray-dried mannitol", the friability is always under 0.5% (See page 4, lines 23-24) "The tablets of the invention have a friability of below 0.5%, preferably below 0.2%, as specified by Ph. Eur. 2.9.7." In contrast, Martani discloses in Tables IV and V, Example 5, direct compression dextrose instead of spray-dried mannitol, wherein the friability is increased until 0.84%. Accordingly, one skilled in the art would not expect spray-dried mannitol to achieve such a friability, especially not at a quantity of at least 59.5% of the tablet.

In view of the amendments made herein and the remarks above, applicant maintains that claims 1-4 and 9 as now amended are not obvious over Martani. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

Reconsideration and allowance of the claims herein is respectfully requested.

Respectfully submitted,

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